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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,304	06/27/2003	Michel J. N. Cormier	33392-714.201	8982
66956 7590 07/27/2007 WILSON SONSINI GOODRICH & ROSATI & MACROFLUX CORP. 650 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,304

Applicant(s)

CORMIER ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2 and 8-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-2 and 8-28 are pending. Applicants amended claims 1, 8, and 15. Applicants cancelled claims 3-7. Claims 24-28 are new. Receipt and consideration of Applicants' new IDS (submitted 5/16/07), amended claim set, and remarks/arguments submitted on May 10, 2007 are acknowledged.

Moot Rejections/objections

All rejections and/or objections of claims 3-7 cited in the previous office action mailed on January 10, 2007 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-3, 5-7, 12, 15-16, and 21 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) **is withdrawn** per Applicants' claim amendments requiring that the wetting agent be an amphiphilic wetting agent.

Response to Arguments

Applicant's arguments, see pages 8-9, filed May 10, 2007, with respect to the rejection of claims 1-3, 5-7, 12, 15-16, and 21 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) have been fully considered and are persuasive. The rejection of claims 1-3, 5-7, 12, 15-16, and 21 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) has been withdrawn.

The rejection of claims 8-10, 13, 17-18, and 22 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) and further in view of Baum (U.S. Patent No. 6,294,515) **is maintained** for the reasons of record set forth on pages 4-8 of the previous office action mailed on June 14, 2006 and further articulated below. Claims

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1-2 are appended to this rejection for the reasons of record. In summary, **claims 1-2, 8-10, 13, 15-16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) in view of Baum (U.S. Patent No. 6,294,515).**

Response to Arguments

Applicant's arguments filed May 10, 2007 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that (1) Trimmer allegedly does not teach a method of treating the surface of microprotrusions, and this deficiency is not cured by the teachings of Baum; (2) the rinse agents described by Baum may or may not be relevant to treating the surface of a material prior to the application of a coating formulation; and (3) the suggestion to include the rinse agents of Baum allegedly does not capture the steps of Applicants' claimed invention.

The Examiner respectfully disagrees with Applicants' traversal arguments. Traversal argument (1) was addressed previously on pages 4-6 of the office action mailed on January 10, 2007 and is incorporated herein by reference. Regarding traversal arguments (2) and (3), it is noted that Applicants' claimed wetting agent reads on any soap or rinse agent used to clean a surface. Applicants' claimed step comprising the treatment of a surface with an amphiphilic wetting agent essentially reads on cleaning a surface with "soap/detergent" (i.e. any amphiphilic molecule, such as a surfactant). It would have been prima facie obvious to an ordinary skilled artisan at the time of the instant invention that soap, such as the rinse agents taught by Baum, can be used to treat a surface. An ordinary skilled artisan would have had a reasonable expectation of success in cleaning a surface prior to coating using "soap/detergent", because this is a well-

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known use of "soap/detergent." Applicants have provided no data or persuasive arguments as to why an ordinary skilled artisan would not have a reasonable expectation of success of cleaning a surface with soap prior to coating said surface with a coating formulation. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 24-28 are rejection under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) in view of Haji et al. (US 2001/0018272).

Applicant Claims

Applicants claim a method of coating a surface or one or more microprojections of a microprojection array comprising (i) providing a microprojection array, (ii) treating the surface with a method selected from the group consisting of chemical pre-etching, plasma treatment, heat treating, and rinsing with an alkaline detergent (iii) providing a coating formulation, and (iv) applying said coating formulation to said treated surface, and (v) drying the coating formulation onto said surfaces to form a coating.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Trimmer were set forth on pages 3-6 of the office action mailed on June 14, 2006. In brief, Trimmer teaches methods of introducing a biological material (i.e. active material) into a predetermines target cell comprising providing (a) a plurality

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of inert microprobes (i.e. microprojections), (b) a solid or quasi-solid mass of target cells defining an interface with the microprobes, and (c) a biological material at the interface, wherein the microprobes may be fabricated from silicon wafers including the following steps: (1) cleaning with a mixture of HCl and hydrogen peroxide; (2) oxidation by heating in an electrically heated quartz furnace; (3) etching in buffered hydrofluoric acid; (4) cascade rinsing; and (5) etching in an aqueous solution of KOH (i.e. an alkaline solution). Trimmer's microprobes are coated with biological materials via standard techniques. It is noted that silicon is a known semiconductor.

Haji teaches a plasma treatment apparatus/method and that **plasma treatment is known for etching the surface of semi-conductor wafer and cleaning a surface of a printed circuit board** (title; abstract; [0002]). An exemplary mixture for plasma etching gases includes a mixture of SF₆ and He gases [0051].

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Trimmer lacks the teaching of plasma treating a surface prior to coating. This deficiency is cured by the teachings of Haji.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention that plasma treating a silicon substrate, such as the substrate used by Trimmer to make microprobes, prior to coating would essentially clean the surface of any undesirable organic compounds and remove any native oxide present on the silicon

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surface. An ordinary skilled artisan would have been motivated to modify the teachings of Trimmer to utilize plasma treatment as an alternative or even supplemental pre-conditioning treatment prior to application of a coating formulation, because this is an art recognized conventional step. It would have been apparent to the ordinary skilled artisan that exposure of the fabricated microprojections to any of the methods taught by Trimmer or plasma treatment taught by Haji, albeit for shorter periods of time than those required in fabrication, would remove extraneous impurities and yield a "clean" surface ideally suited for coating. A skilled artisan would have had a reasonable expectation of successfully forming a film of the biological materials taught by Trimmer on his invented microprobes, because plasma treatment is well known as being able to etch silicon surfaces, and the step of drying a coating formulation is conventional in the formation of coatings. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

Claims 11, 15-16, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) and further in view of Jain et al. (U.S. Patent No. 4,505,890) and/or Patel et al. (U.S. Patent No. 6,248,363).

Applicant Claims

Applicants claim a method of coating a surface or one or more microprojections of a microprojection array comprising (i) providing a microprojection array, (ii) providing a coating formulation comprising an active agent and an amphiphilic wetting

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agent, (iii) applying said coating formulation to said treated surface, and (iv) drying the coating formulation onto said surfaces to form a coating.

***Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)***

The teachings of Trimmer and Jain were set forth on pages 3-6 and 9-11 of the office action mailed on June 14, 2006. Patel teaches encapsulation coating formulations for solid substrates (e.g. tablets) comprising different combinations of pharmaceutical active ingredients, hydrophilic surfactant, lipophilic surfactants, and triglycerides (abstract). Suitable active agents are taught from col. 4, line 35 through col. 10, line 41. Patel teaches that it is known that both lipophilic and hydrophilic surfactants are known to be useful **for improving both the physical and chemical stability of active ingredients** as well as enhancing absorption and bioavailability (col. 10, lines 42-64). Patel provides a variety of lipophilic and hydrophilic surfactants as well as the corresponding HLB values, if known: polyethoxylated fatty acids (Table 1, col. 12-col. 14), PEG-fatty acid diesters (Table 2, col. 13, line 40 through col. 15, line 12), PEG-fatty acid mono- and di-ester mixtures (Tables 3 and 4, col. 15, line 12 through col. 16, line 44), alcohol-oil transesterification products (Table 5, col. 16, line 45 through col. 18, line 67), polyglycerized fatty acids (Table 6, col. 19), propylene glycol fatty acid esters (Table 7, col. 19), mixtures of propylene glycol esters-glycerol esters (Table 8, col. 21, lines 1-20), mono- and di-glycerides (Table 9, col. 22, line 1 through col. 23, line ~10), sterol and sterol derivatives (Table 10, col. 23, line ~10), PEG-sorbitan fatty acid esters (Table 11, col. 24, lines 30-67), PEG-alkyl ethers (Table 12, col. 25, line 1-25), sugar esters (Table

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13, col. 25, line 25-43), PEG alkyl phenols (Table 14, col. 25, lines 43-60), **polyoxyethylene-polyoxypropylene block copolymers (i.e. poloxamers)** (Table 15, col. 25, line 60 through col. 27, line 33), sorbitan fatty acid ester surfactants (Table 16, col. 27, lines 35-54), and lower alcohol fatty acid esters (Table 17, col. 27, line 55 through col. 28, line 10).

*Ascertainment of the Difference Between Scope the Prior Art and the Claims.
(MPEP §2141.012)*

Trimmer lacks the express teaching of treating a coating a surface with a coating formulation comprising an amphiphilic wetting agent and an active agent. This deficiency is cured by the teachings of Jain and Patel et al.

*Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)*

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Trimmer and Jain, because Trimmer suggests that the inclusion of wetting agents to the solution of biological material, or to the medium in which the method is carrier out would enhance the wetting of the surface of his invented microprobes via the formation of a meniscus. Trimmer's suggestion to include wetting agents to the solution of biological material used to coat his invented microprobes would have provided the artisan with the motivation to combine the teachings of Trimmer and Jain, because HPMC is a wetting agent and Jain teaches a coating composition comprising HPMC. A skilled artisan would have had a reasonable expectation of success upon combination because HPMC is a well-known compound

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used in coating formulations, and Trimmer suggested the inclusion of wetting agents in coating formulations comprising a biological material. As optional ingredients, such as stabilizers (Jain, col. 4, line 25) one could include the surfactants taught by Patel, because surfactants are also known as stabilizers of active ingredients. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because Trimmer teaches the coating of microprobes, Jain teaches coating compositions comprising a mixture of active ingredients and amphiphilic wetting agents (i.e. surfactants), and Patel teaches known surfactants. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

Response to Arguments

Applicant's arguments with respect to claims 11, 15-16, 19-21, and 23 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

Applicant is advised that should claims 8-9 be found allowable, claims 17-18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 17-18 are identical to claims 8-9, respectively.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,855,372 (USPN '372) in view of Trimmer et al. (WO 96/10630) and Baum (U.S. Patent No. 6,294,515) for the reasons of record set forth on pages 11-12 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that none of the claims of USPN '372 teach a step of treating the surface of one or more microprotrusions selected from the group including rinsing with an amphiphilic wetting

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agent and that the teachings of Trimmer do not cure this deficiency. The Examiner respectfully disagrees, because, as Applicants' admitted and as the Examiner has further articulated above in the instant application, Trimmer does teach a method of pre-treating a surface. Furthermore, the combination of Trimmer and Baum does teach a method of treating a surface with an amphiphilic wetting agent. As stated above, the treatment of a surface with "soap/detergent" would have reasonably been expected to clean said surface, which common sense suggests is desirable prior to coating a surface.

Other Matter

It is noted that phrases stating, "the wetting agent comprises...species (e.g. a surfactant)" are potentially indefinite, because said phrases do not clearly set forth the identity of the required wetting agent. Amending these claims to read, "the wetting agent is...would remove any doubt as to the identity of the claimed wetting agent.

Conclusion

Claims 1-2 and 8-28 are rejected. No claims are allowed.

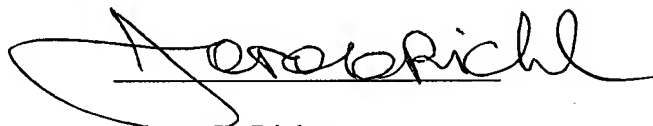
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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